US008617123B2

(12) **United States Patent**
Hottovy et al.

(10) **Patent No.: US 8,617,123 B2**
(45) **Date of Patent: Dec. 31, 2013**

(54) **PRE-FILLED ACTIVE VIAL HAVING INTEGRAL PLUNGER ASSEMBLY**

(75) Inventors: **Tracy Ray Hottovy**, Wilson, NC (US); **Eric Schiller**, Westfield, NJ (US)

(73) Assignee: **Becton Dickinson France, S.A.S.**, Le Pont-de-Claix (FR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 464 days.

(21) Appl. No.: **12/859,808**

(22) Filed: **Aug. 20, 2010**

(65) **Prior Publication Data**

US 2011/0066116 A1 Mar. 17, 2011

Related U.S. Application Data

(60) Provisional application No. 61/235,836, filed on Aug. 21, 2009.

(51) **Int. Cl.**
A61M 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/208**; 222/23; 222/263; 222/389; 222/401; 222/477

(58) **Field of Classification Search**
USPC 60/387, 409; 222/23, 41, 61, 256, 222/260–263, 389, 477, 401; 138/43; 251/208
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

927,298	A *	7/1909	Twitchell	73/744
1,961,490	A	6/1934	Hein	
2,630,804	A	3/1953	Mende	
3,604,417	A	9/1971	Stolzenberg et al.	
3,780,693	A *	12/1973	Parr	116/270
4,093,108	A	6/1978	Hein et al.	
4,113,144	A	9/1978	Hein et al.	
4,221,218	A	9/1980	Pfleger	
4,323,066	A	4/1982	Bourdon	
4,505,701	A	3/1985	Navato	
4,583,978	A	4/1986	Porat et al.	
4,684,366	A	8/1987	Denny et al.	
4,773,900	A	9/1988	Cochran	
4,915,693	A	4/1990	Hessel	
5,009,637	A	4/1991	Newman et al.	
5,017,190	A *	5/1991	Simon et al.	604/207
5,041,094	A	8/1991	Perego et al.	
5,053,019	A	10/1991	Duffy	
5,140,982	A *	8/1992	Bauman	128/205.13
5,312,389	A	5/1994	Theeuwes et al.	
5,779,678	A	7/1998	Carter	

(Continued)

FOREIGN PATENT DOCUMENTS

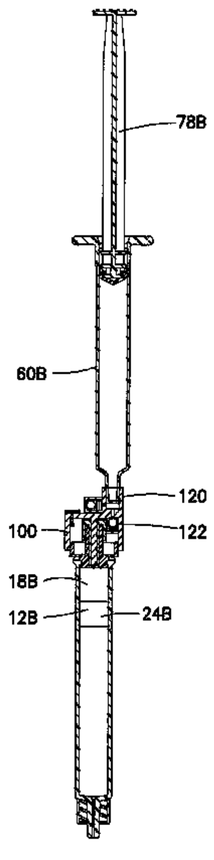
EP	0 600 754 A2	6/1994
EP	1 208 858 A1	5/2002
EP	1 535 639 A1	6/2005

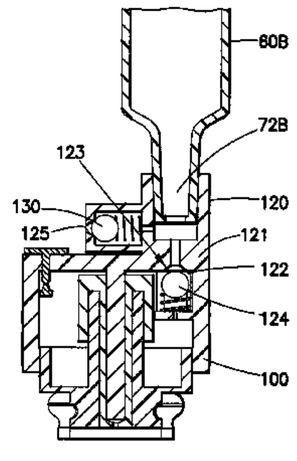
Primary Examiner — Kevin P Shaver
Assistant Examiner — Patrick M Buechner
(74) *Attorney, Agent, or Firm* — The Webb Law Firm

(57) **ABSTRACT**

A pre-filled vial assembly adapted for dispensing and delivering a fluid includes: a body member having a distal end, a proximal end, and a sidewall extending therebetween defining an interior; and a transitionable stopper disposed within the interior of the body member. At least a portion of the body member is engageable with a source of air or fluid for advancing the transitionable stopper from an initial position to an activated position in which at least a portion of a fluid contained within the interior of the body member is advanced therefrom.

10 Claims, 11 Drawing Sheets





(56) **References Cited**

U.S. PATENT DOCUMENTS

5,868,713	A	2/1999	Klippenstein	
5,879,336	A	3/1999	Brinon	
5,954,695	A	9/1999	Sims et al.	
6,123,685	A	9/2000	Reynolds	
6,139,530	A	10/2000	Hiejima et al.	
6,331,173	B1	12/2001	Ljungquist	
6,685,673	B2	2/2004	Minezaki et al.	
6,890,320	B2	5/2005	Minezaki	
7,374,556	B2	5/2008	Mallett	
2002/0165490	A1	11/2002	Minezaki et al.	
2003/0216695	A1	11/2003	Yang	
2003/0233070	A1*	12/2003	De La Serna et al.	604/141
2004/0019325	A1	1/2004	Shekalim	
2005/0070848	A1	3/2005	Kim et al.	
2009/0177158	A1	7/2009	Krumme et al.	

* cited by examiner

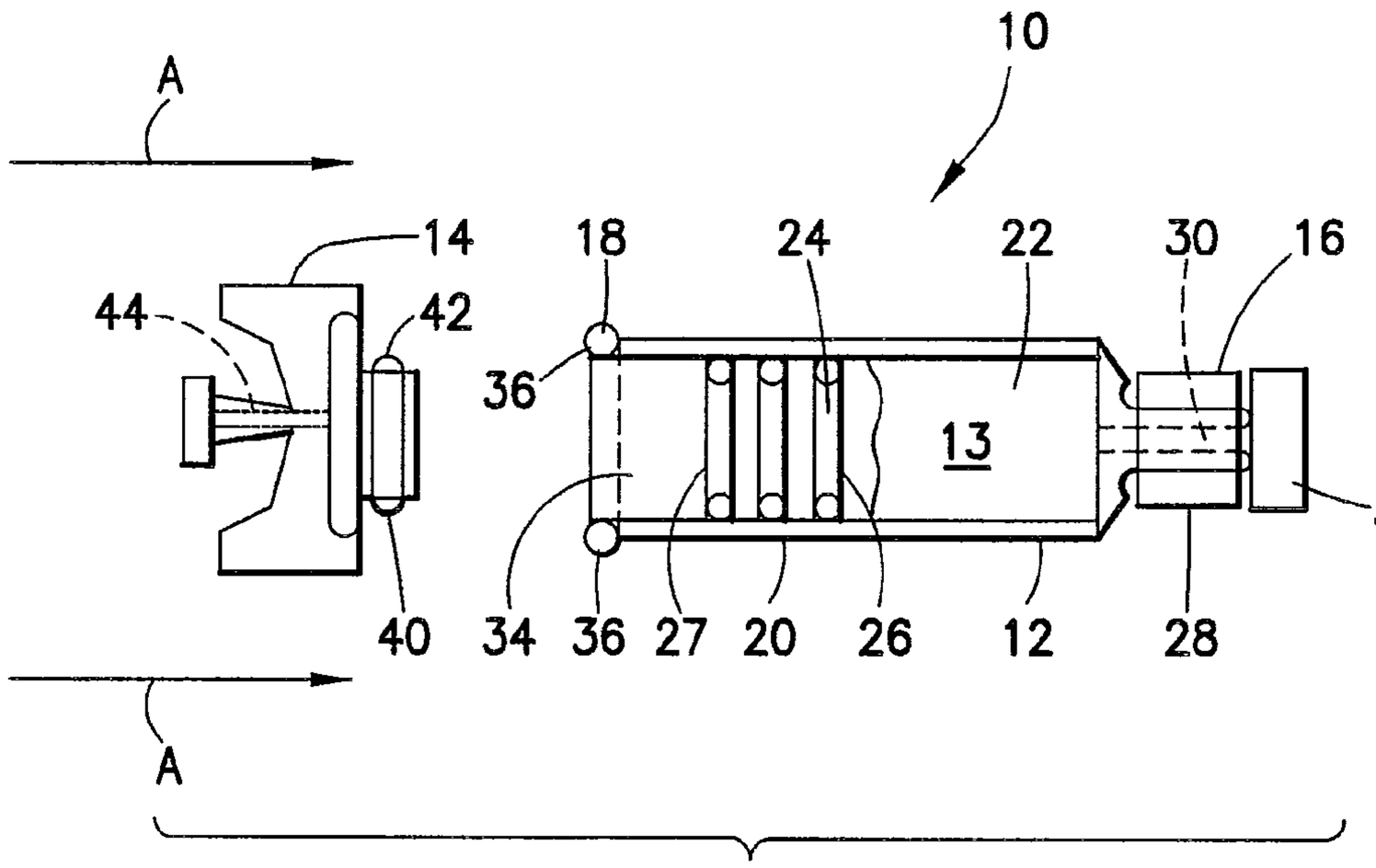

A
10
14
18
24
22
30
16
44
42
36
13
32
40
34
36
27
20
26
12
28
A

FIG.1

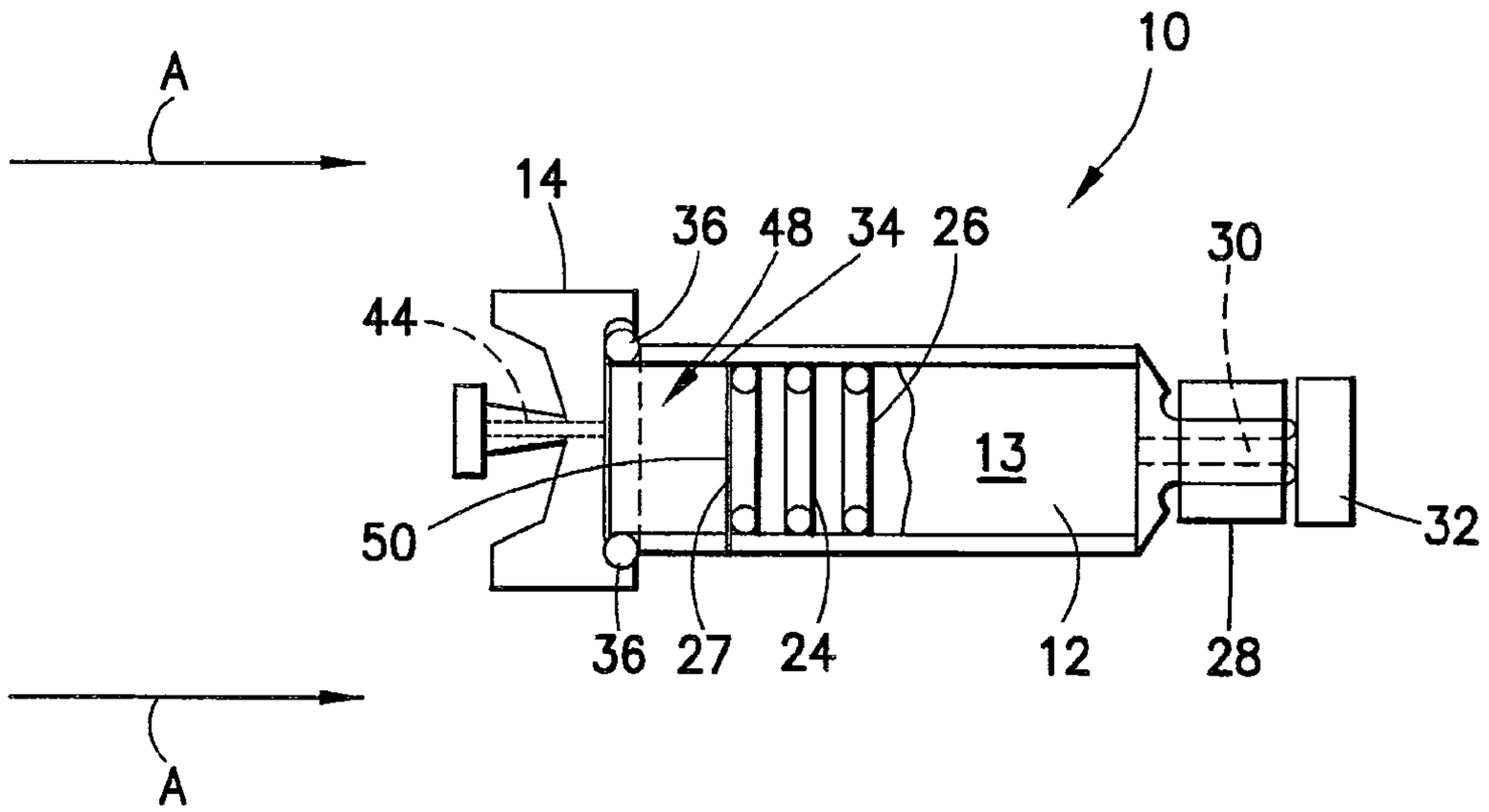

A
10
14
36
48
34
26
30
44
13
50
32
36
27
24
12
28
A

FIG.2

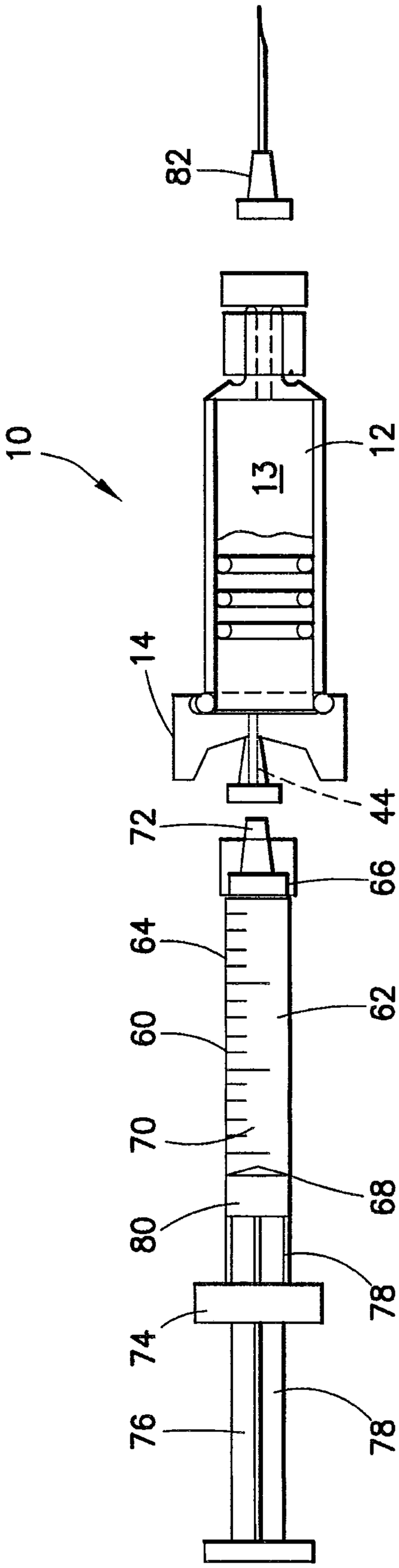

82
10
13
12
14
44
72
66
64
62
60
70
68
80
78
74
76
78

FIG.3

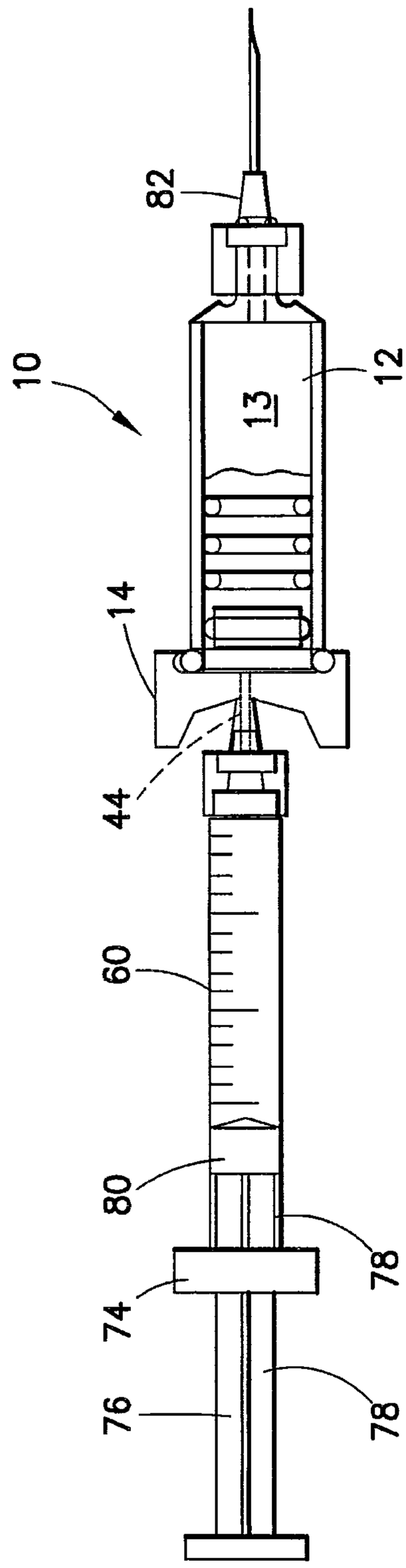

82
10
13
12
14
44
60
80
78
74
76
78

FIG.4

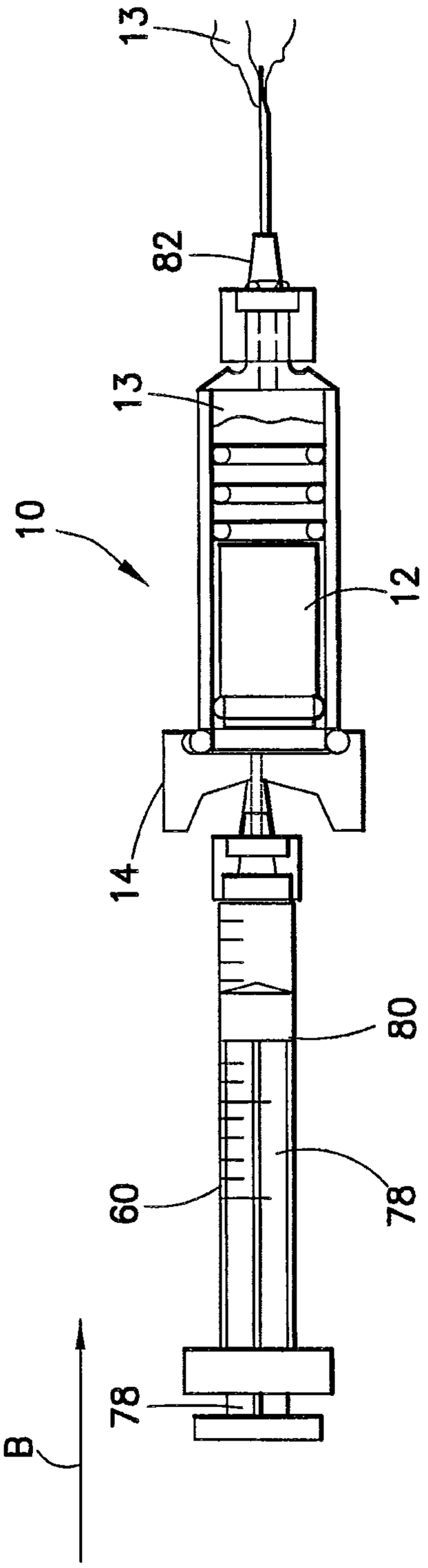


FIG.5

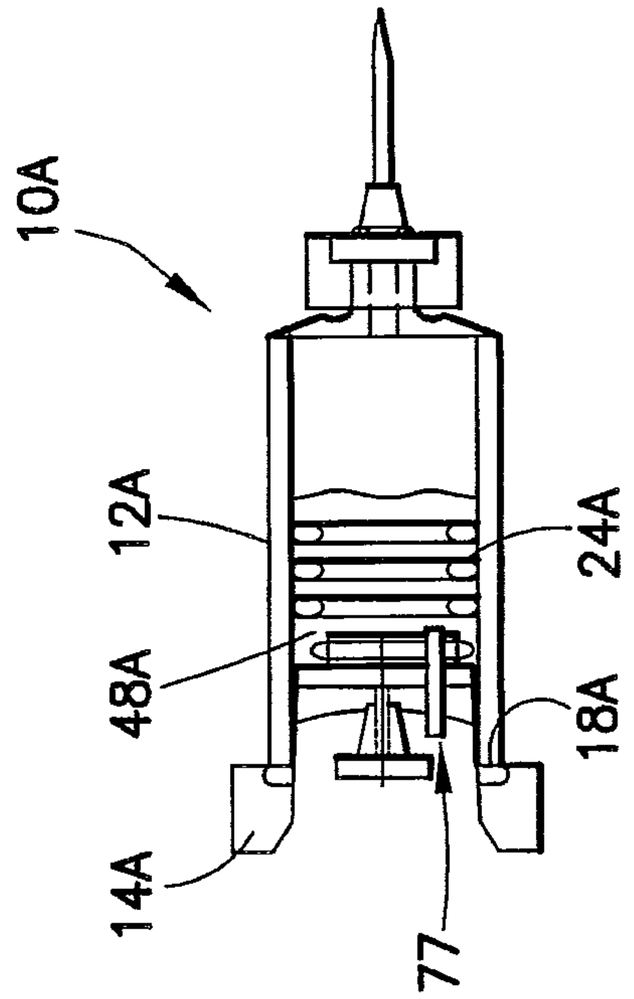


FIG.7

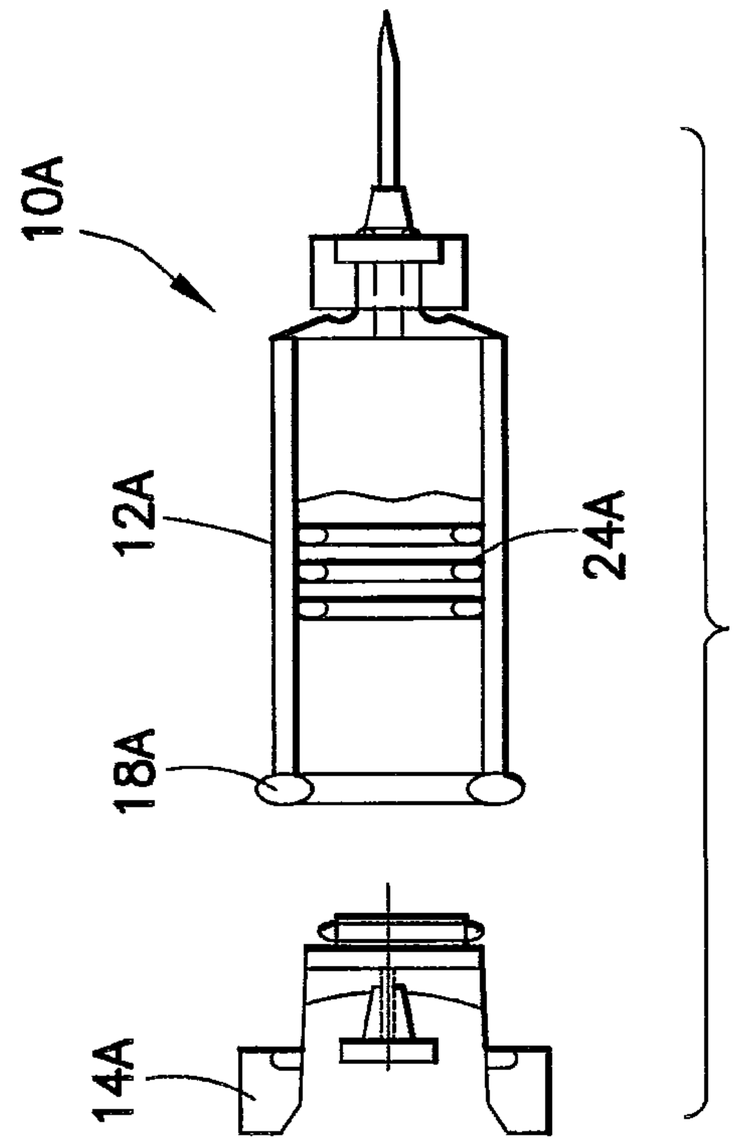


FIG.6

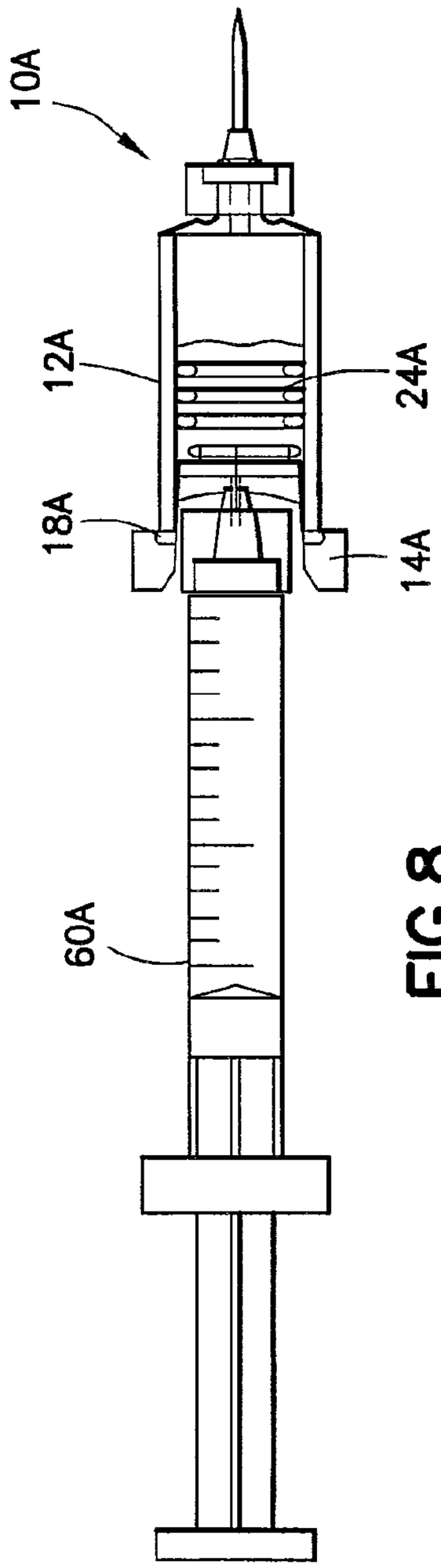


FIG.8

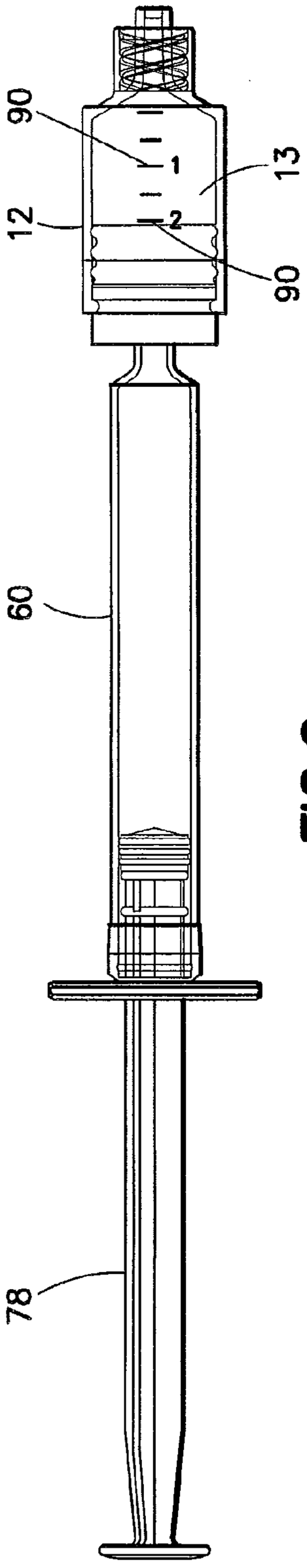


FIG.9

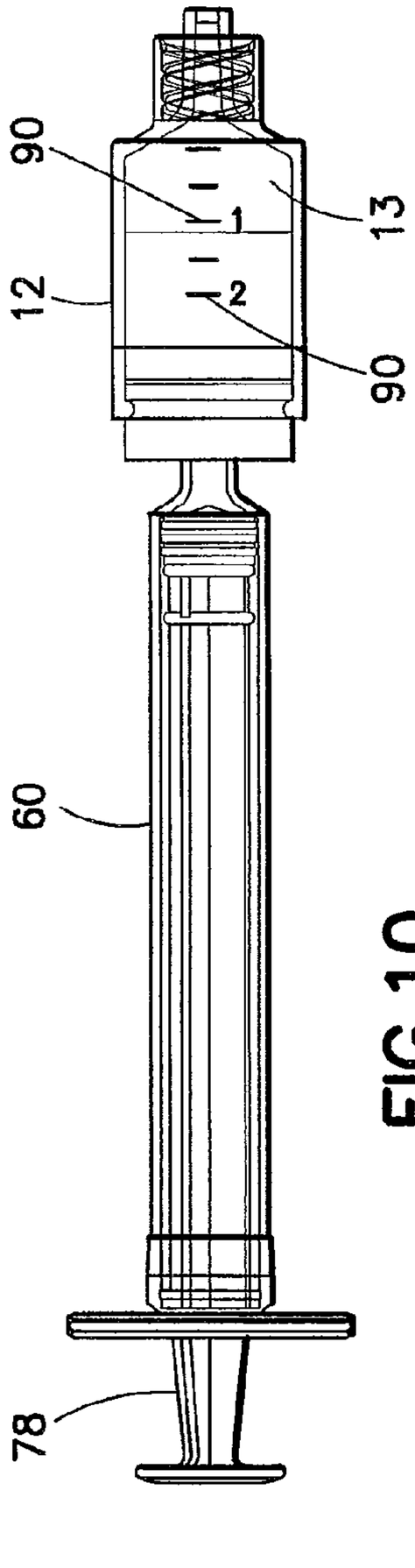


FIG.10

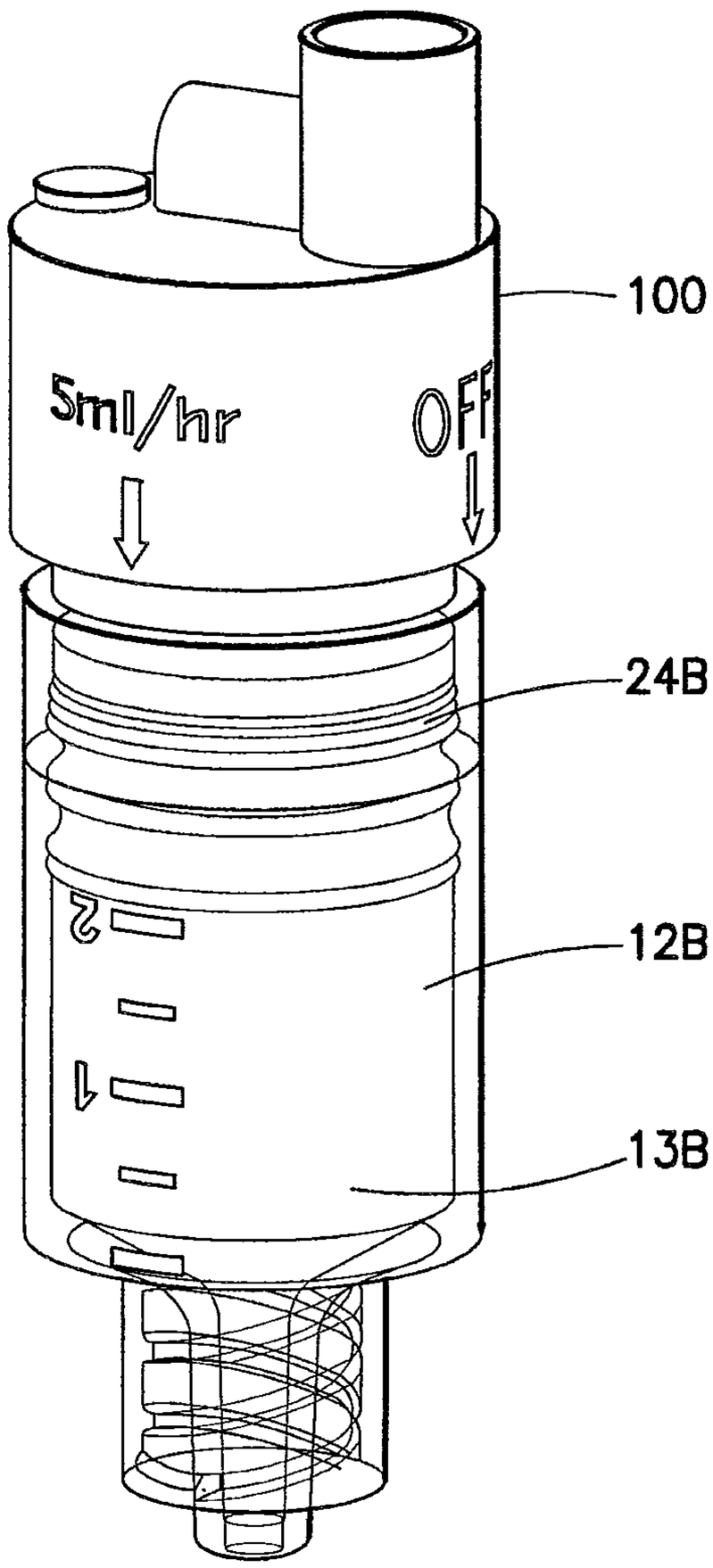


FIG.11

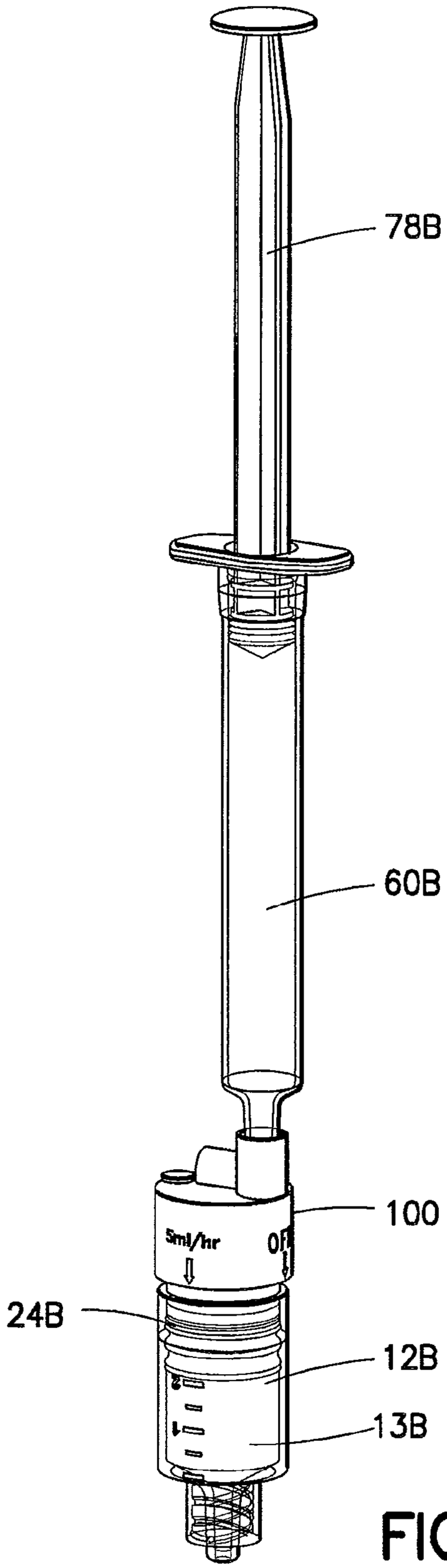

78B
60B
100
5ml/hr
Off
24B
12B
13B

FIG.12

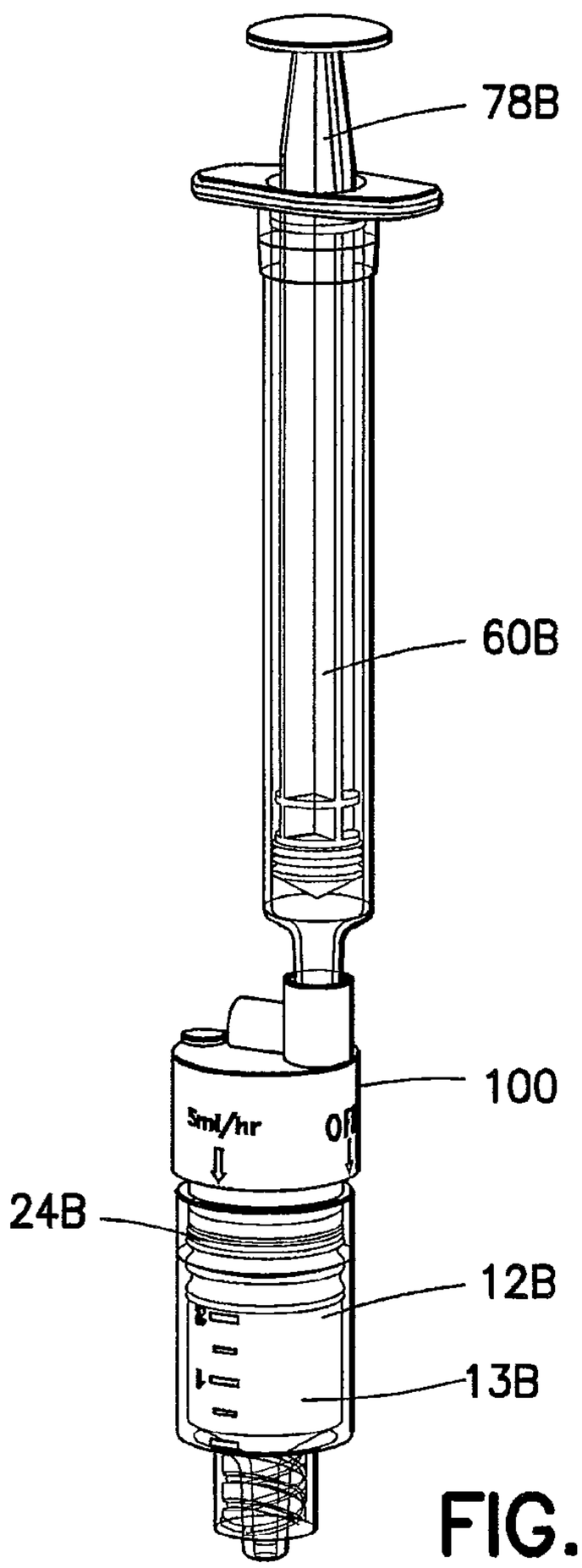

78B
60B
100
5ml/hr
Off
24B
12B
13B

FIG.13

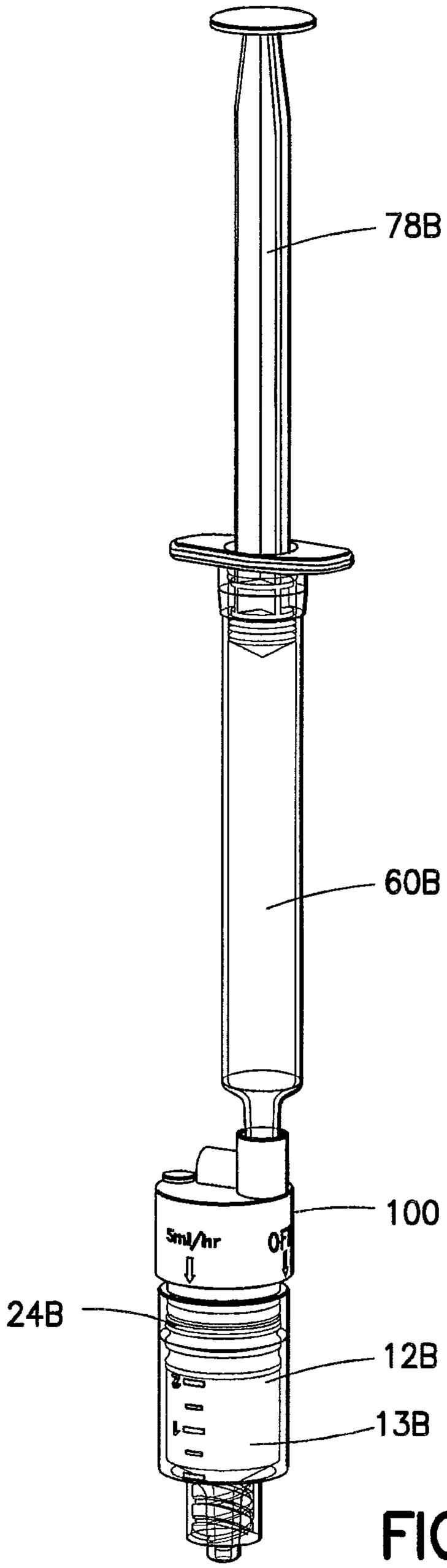

78B
60B
100
5ml/hr
OFF
24B
12B
13B

FIG.14

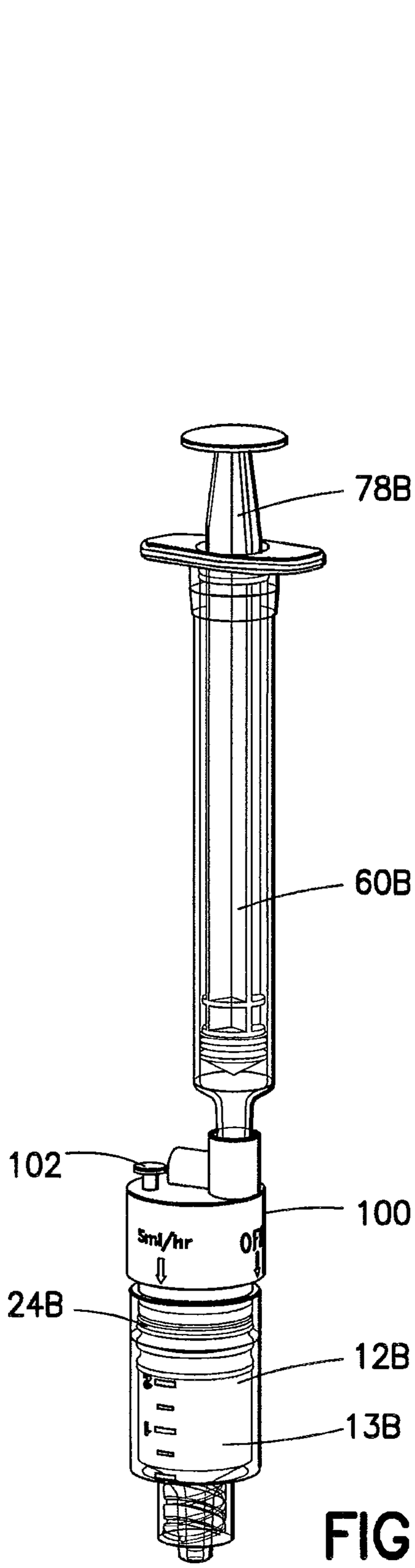

78B
60B
102
100
5ml/hr
OFF
24B
12B
13B

FIG.15

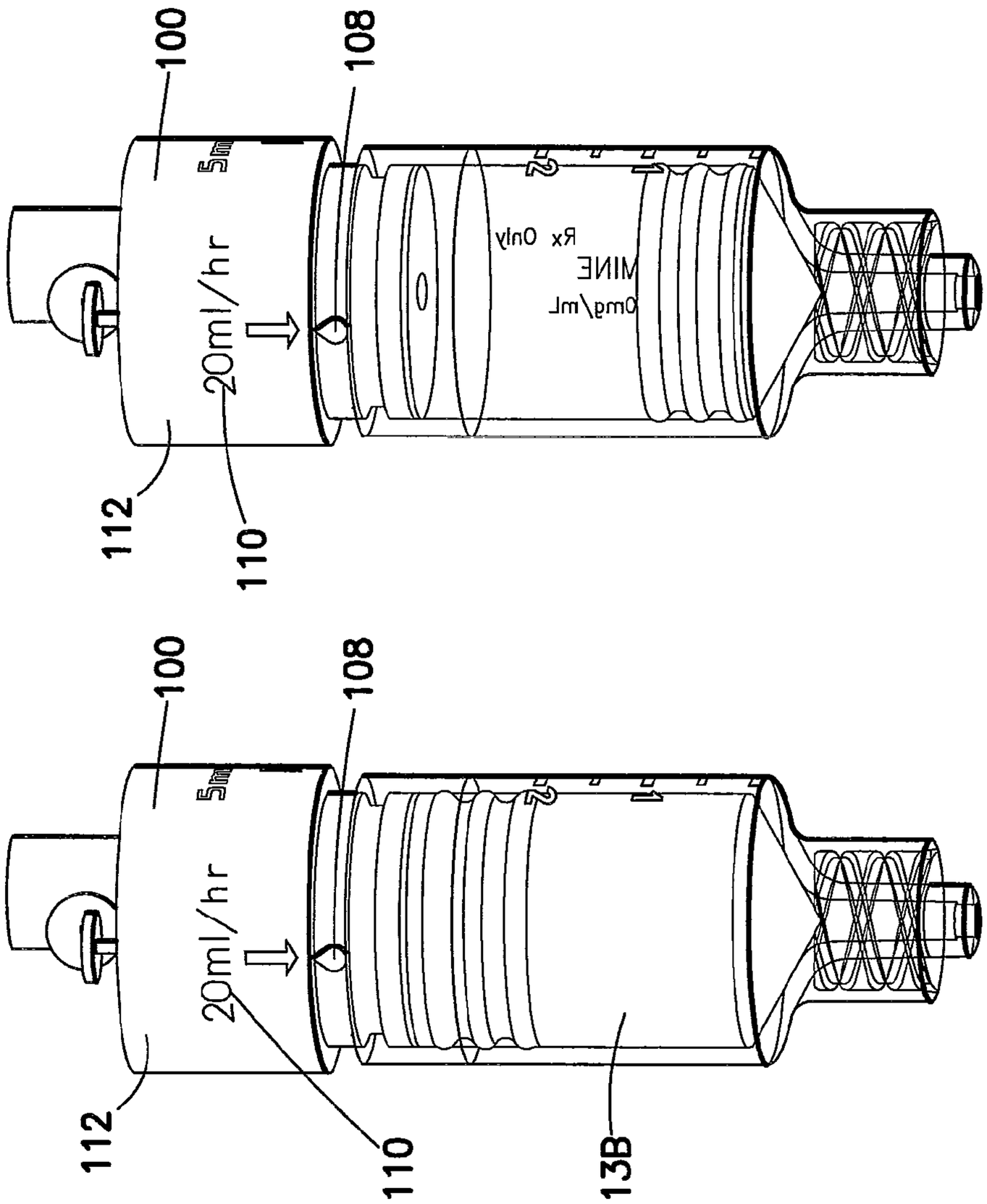


FIG.18

FIG.17

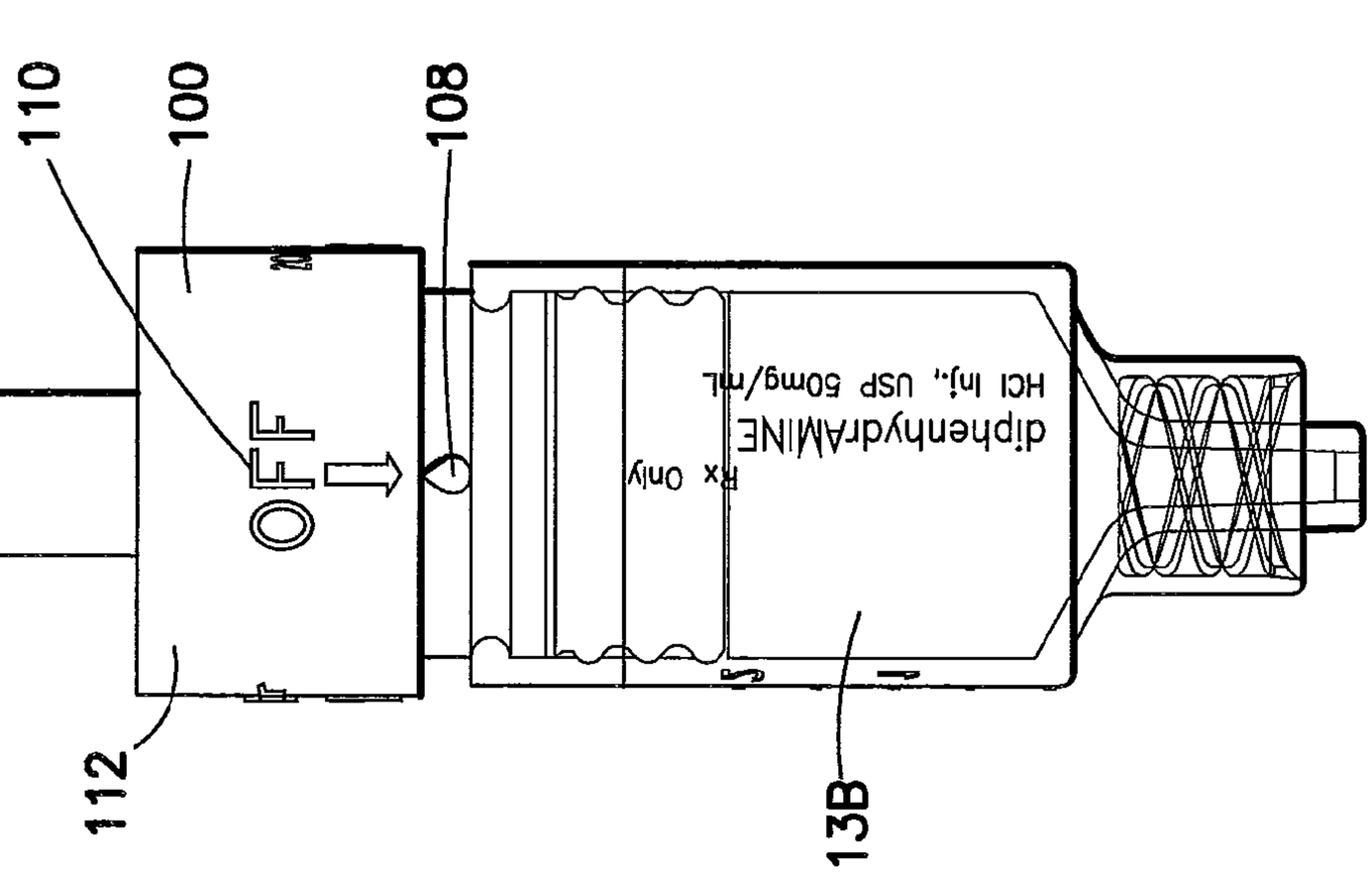


FIG.16

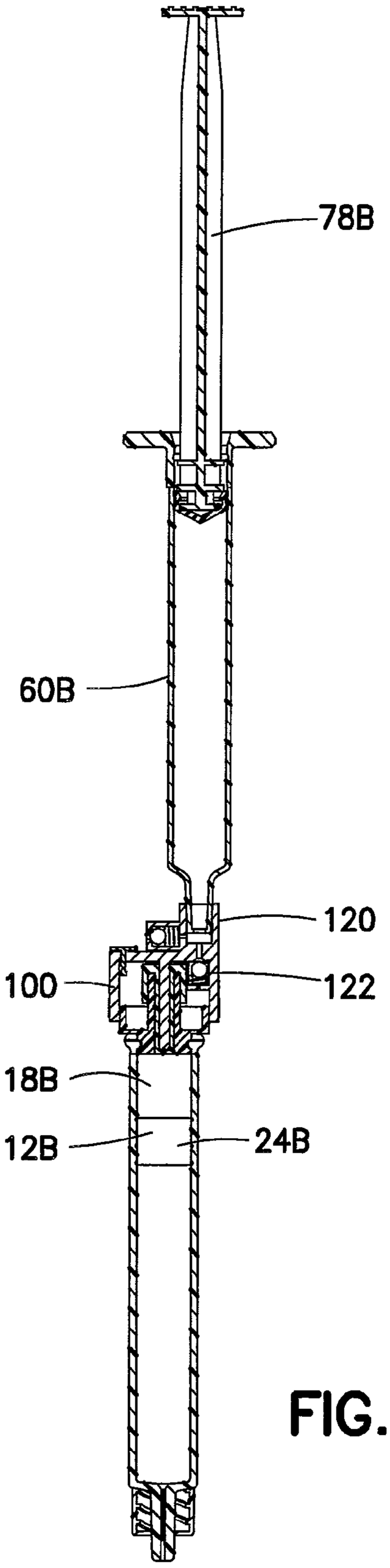

78B
60B
120
100
122
18B
12B
24B

FIG.19

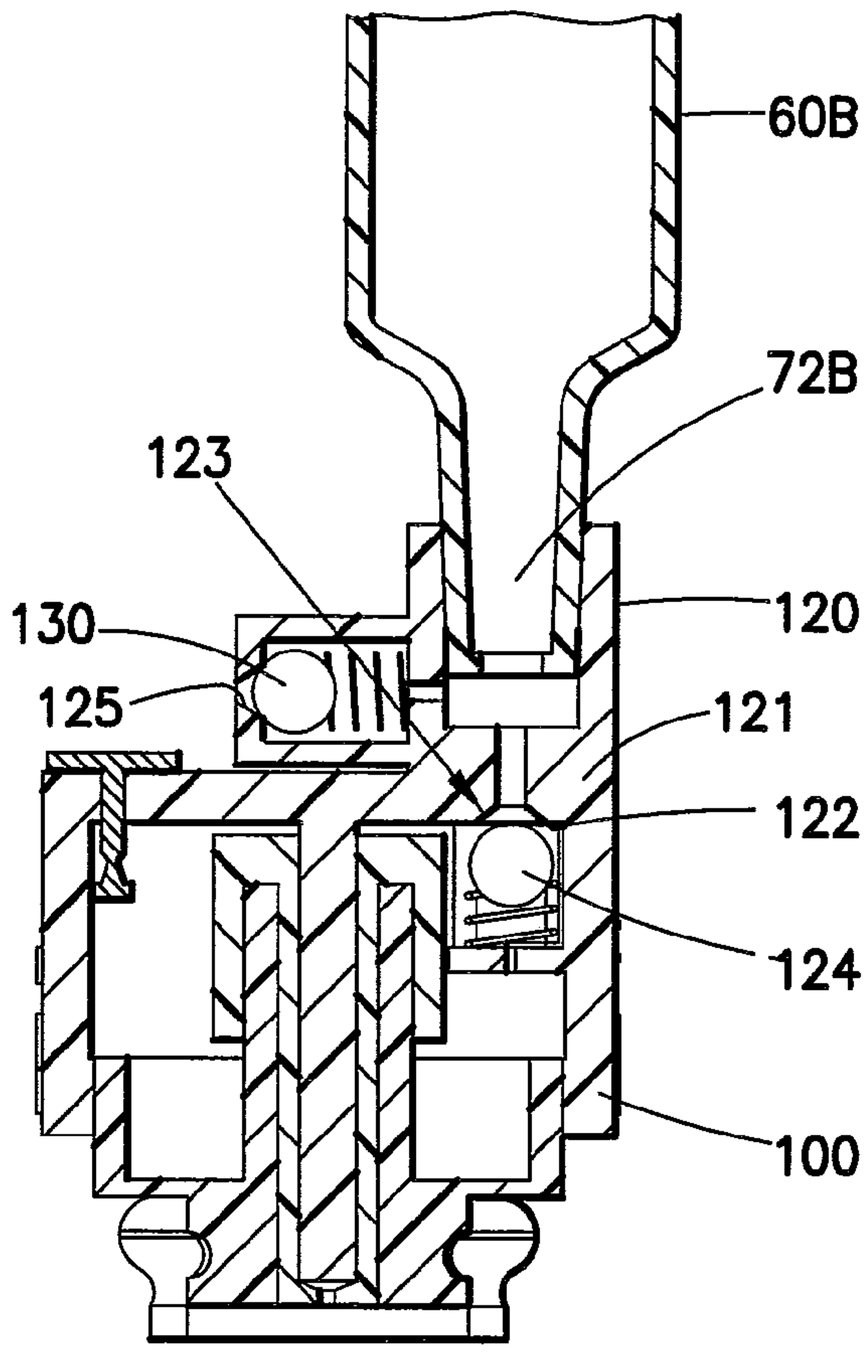

60B
72B
123
130
120
125
121
122
124
100

FIG.20

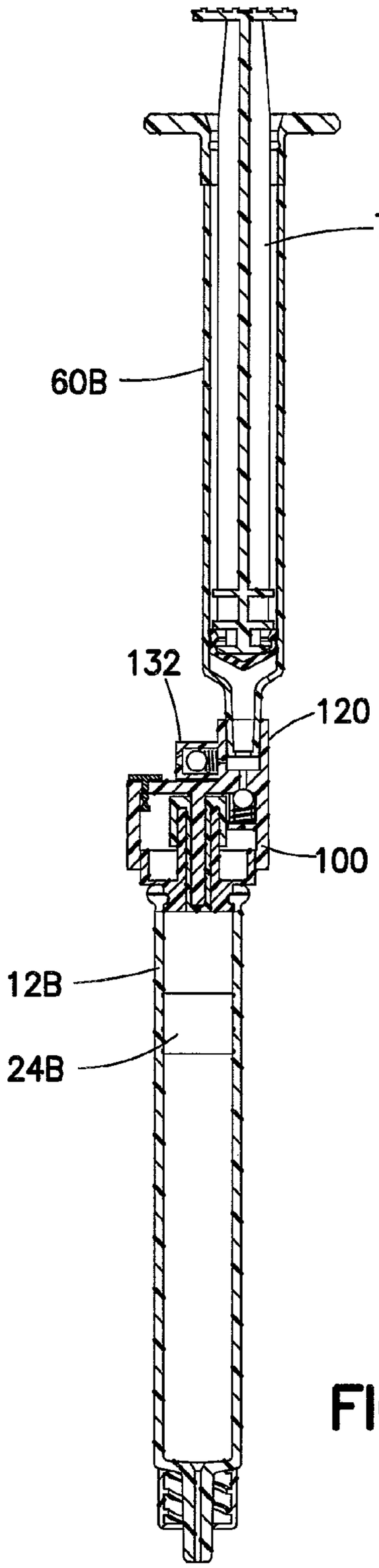

78B
60B
132
120
100
12B
24B

FIG.21

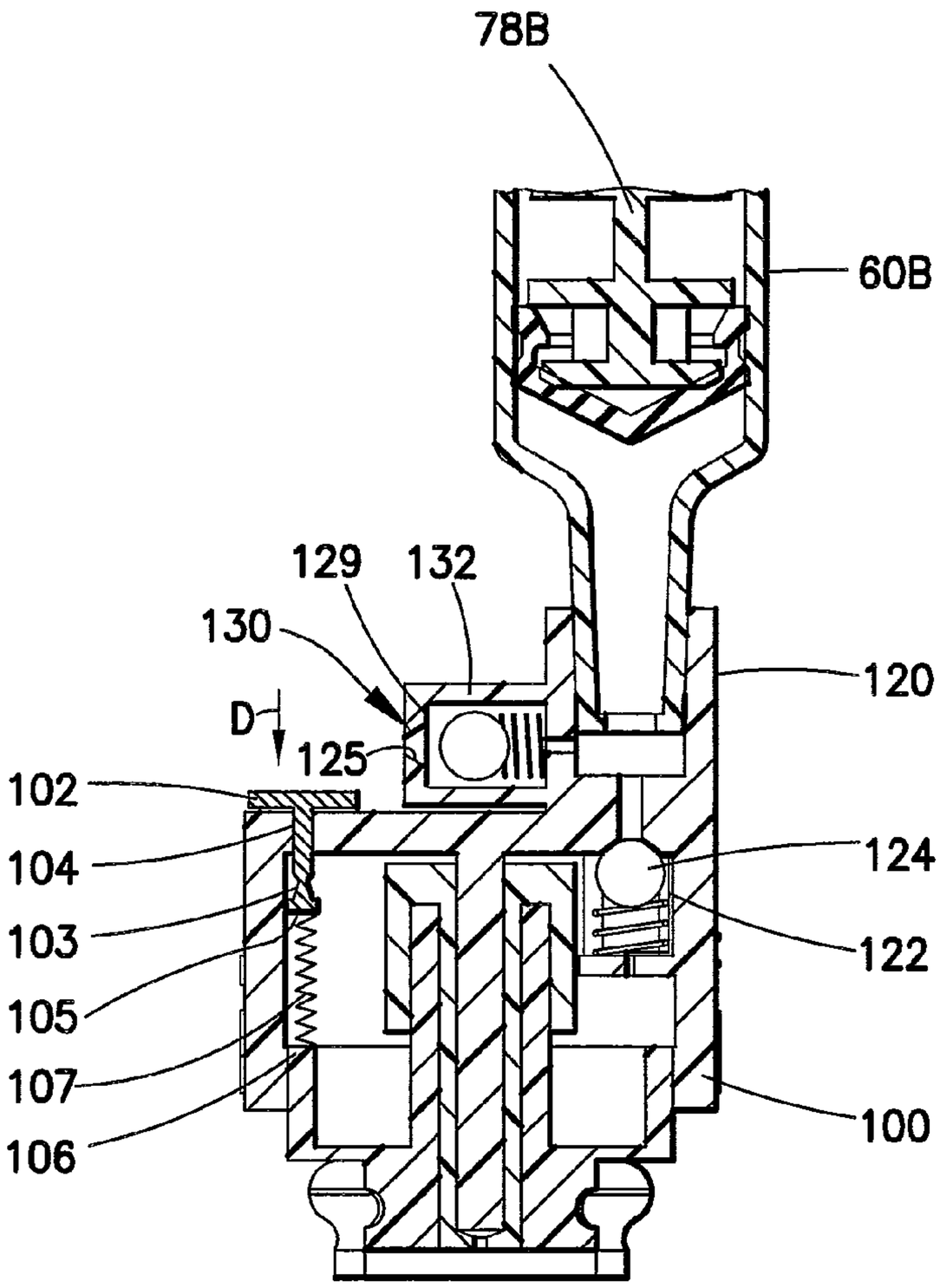

78B
60B
129
132
130
120
D
125
102
104
124
103
122
105
107
100
106

FIG.22

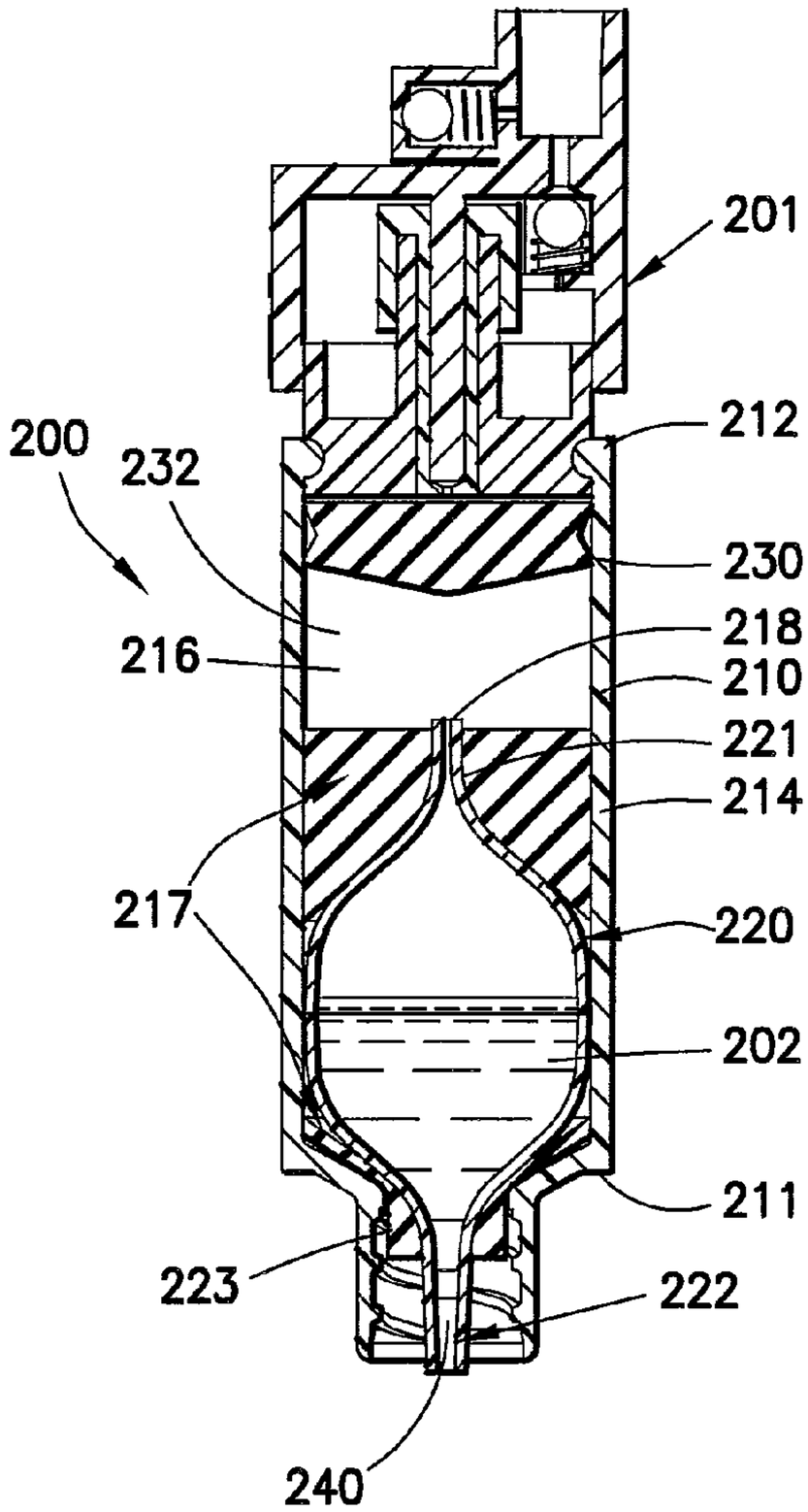

201
212
200
232
230
216
218
210
221
214
217
220
202
211
223
222
240

FIG.23

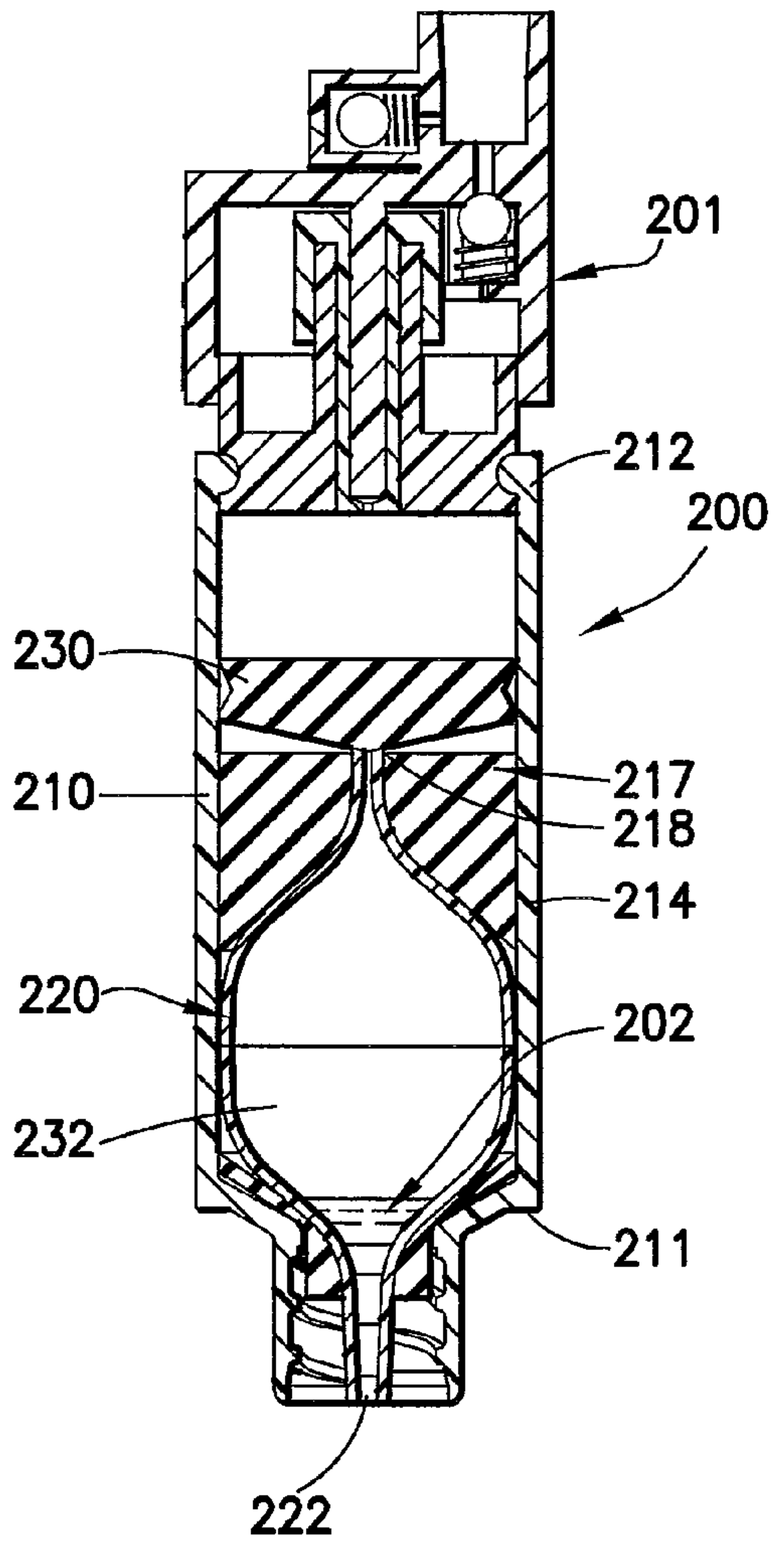

201
212
200
230
210
217
218
214
220
202
232
211
222

FIG.24

PRE-FILLED ACTIVE VIAL HAVING INTEGRAL PLUNGER ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application Ser. No. 61/235,836 entitled "Pre-Filled Active Vial Having Integral Plunger Assembly" filed Aug. 21, 2009, the entire disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to a pre-filled vial assembly adapted for dispensing and delivery of a fluid. More particularly, the present invention is directed to a pre-filled active vial having an integral plunger assembly for delivering a fluid that may be directly attached to a standard hypodermic syringe. A regulator for regulating the release of air from the pre-filled vial assembly is also disclosed.

2. Description of Related Art

Syringe assemblies, and in particular hypodermic syringes, are well known in the medical field for dispensing fluids, such as medication. A conventional syringe typically includes a syringe barrel with an opening at one end and a plunger mechanism disposed through the other end. The plunger typically includes a plunger rod extending through the barrel, with a plunger head or stopper at the end of the plunger rod within the barrel and with a finger flange at the other end of the plunger rod extending out of the barrel. In use, the plunger rod is retracted through the syringe barrel to fill the syringe barrel with a fluid, such as a medication, with the plunger rod extending out from the rear end of the syringe barrel. For delivery of the medication to a patient, the opening of the syringe barrel is adapted for fluid communication with a patient, such as through a hypodermic needle fitted at the front end of the syringe barrel or through a luer-type fitting extending from the front end of the syringe barrel for attachment with a fluid line of a patient. Upon depressing of the plunger rod, the plunger rod and stopper travel through the syringe barrel, thereby forcing the contents of the syringe out through the opening at the front end for delivery to the patient. Such an operation is well known in the medical field, and medical practitioners have become well accustomed to the use of such common fluid delivery procedures through standard syringes.

Conventional syringes are well known to be used in connection with a vial of a medication, where the user draws the fluid into the syringe immediately prior to injection and delivery of the fluid to the patient. Oftentimes, hypodermic syringes may be packaged as "pre-filled" devices, wherein the syringe is pre-filled with medication prior to being packaged and delivered to the end user. In this manner, there is no need for the user to fill the device prior to injection, thereby saving time for the end user and maintaining consistent volumes for delivery.

Pre-filled syringes and pre-filled metered dose syringes are often filled with narcotics or other drugs at a production facility, packaged, and then shipped to a medical facility. Once at the facility, these syringes are often placed in controlled storage and/or locked cabinets to reduce theft of the syringes themselves and/or theft of the contents of these syringes. The space within these controlled storage locations is often limited, thus there is a need for a syringe assembly

that has a smaller packaging footprint, to reduce the storage space required for containing this syringe.

For some applications, small vials and ampoules are used to store medications and other narcotics or controlled substances. These vials and ampoules are typically storage vessels and do not typically include a plunger rod or stopper. During use, a medical practitioner draws the medication or controlled substance from the vial or ampoule by inserting the needle of a standard syringe therein and withdrawing the contents. The process of transferring the contents of a vial or ampoule into a syringe for injection increases the likelihood of contamination. In addition, as the majority of ampoules are glass, the transfer process increases the likelihood that shards of glass may become incorporated into the injected fluid.

SUMMARY OF THE INVENTION

In accordance with an embodiment of the present invention, a pre-filled vial assembly adapted for dispensing and delivering a fluid includes: a body member having a distal end, a proximal end, and a sidewall extending therebetween defining an interior; and a transitionable stopper disposed within the interior of the body member. At least a portion of the body member is engageable with a source of air or fluid for advancing the transitionable stopper from an initial position to an activated position in which at least a portion of a fluid contained within the interior of the body member is advanced therefrom.

The proximal end of the body member may include a receiving cavity. The pre-filled vial assembly may further include a luer connection having a forward end configured for engagement with the receiving cavity of the proximal end of the body member. The forward end of the luer connection may include a seal for internal sealing against a portion of the receiving cavity. At least a portion of the proximal end of the body member may include a sealing member for receipt within a portion of the luer connection.

The luer connection may include a vent. The source of air or gas may be engaged with a fluid passage formed in the luer connection. The source of air or gas may be a standard syringe, such that depression of a plunger rod of the standard syringe transitions the transitionable stopper from the initial position to the activated position to expel contents from the interior of the body member of the pre-filled vial assembly.

The distal end of the body member may include a dispensing tip having a fluid passage therethrough in communication with the interior of the body member. A dispensing cannula may be configured for engagement with the dispensing tip of the body member. The body member may include markings provided on a portion thereof for providing an indication of an amount of fluid that has been expelled during use.

In accordance with another embodiment of the present invention, a pre-filled pod assembly includes: a pre-filled pod having a distal end, a proximal end, and a sidewall extending therebetween defining an interior; a transitionable stopper disposed within the interior of the pre-filled pod; and a regulator coupled to the proximal end of the pre-filled pod and provided in fluid communication with the interior of the pre-filled pod. At least a portion of the regulator is engageable with a source of air or fluid for advancing the transitionable stopper from an initial position to an activated position in which at least a portion of a fluid contained within the interior of the pre-filled pod is advanced therefrom.

The regulator may be configured to apply a predetermined amount of pressurized air to the transitionable stopper through the use of a valve device. The source of air or gas may be engaged with an access port formed in the regulator. The

source of air or gas may be a standard syringe, such that depression of a plunger rod of the standard syringe pressurizes the regulator. The regulator may further include an indicator that is activated to indicate that the regulator has a predetermined amount of pressurized air that is sufficient to deliver a complete dose. The regulator may include an activation trigger configured to be aligned with an indicator for allowing a user to set the regulator to deliver a metered dose.

In accordance with yet another embodiment of the present invention, a pre-filled pod assembly includes: a pre-filled pod having a distal end, a proximal end, and a sidewall extending therebetween defining an interior; and a capsule having a fluid contained therein and disposed within the interior of the pre-filled pod. The capsule includes a first opening adjacent a first end of the capsule and aligned with the proximal end of the pre-filled pod, and a second opening adjacent a second end of the capsule and aligned with the distal end of the pre-filled pod. The pre-filled pod assembly also includes a transitionable stopper disposed within the interior of the pre-filled pod between the proximal end of the pre-filled pod and the first end of the capsule. At least a portion of the pre-filled pod is engageable with a source of air or fluid for advancing the transitionable stopper such that air disposed between the capsule and the transitionable stopper is pressurized and enters the capsule via the first opening, thereby expelling at least a portion of the fluid from within the capsule through the second opening.

At least a portion of the transitionable stopper may seal the first opening after the transitionable stopper has advanced completely. A volume of the fluid within the capsule may be greater than a volume of air disposed between the capsule and the transitionable stopper, which limits expulsion of the air from the capsule of the pre-filled pod. The capsule may be held within the interior of the pre-filled pod in a specific orientation by at least one grommet. In addition, an air bubble may be provided adjacent to the second opening of the capsule to limit expulsion of the fluid within the capsule absent advancement of the transitionable stopper.

In accordance with still another embodiment of the present invention, a pre-filled pod assembly includes: a pre-filled pod having a distal end, a proximal end, and a sidewall extending therebetween defining an interior; and a capsule having a fluid contained therein and disposed within the interior of the pre-filled pod. The capsule includes a first opening adjacent a first end of the capsule and aligned with the proximal end of the pre-filled pod, and a second opening adjacent a second end of the capsule and aligned with the distal end of the pre-filled pod. The pre-filled pod assembly also includes: a transitionable stopper disposed within the interior of the pre-filled pod between the proximal end of the pre-filled pod and the first end of the capsule, and a regulator coupled to the proximal end of the pre-filled pod and provided in fluid communication with the interior of the pre-filled pod. The regulator is engageable with a source of air or fluid for advancing the transitionable stopper such that air disposed between the capsule and the transitionable stopper is pressurized and enters the capsule via the first opening, thereby expelling at least a portion of the fluid from within the capsule through the second opening.

At least a portion of the transitionable stopper may seal the first opening after the transitionable stopper has advanced completely. A volume of the fluid within the capsule may be greater than a volume of air disposed between the capsule and the transitionable stopper, which limits expulsion of the air from the capsule of the pre-filled pod. The capsule may be held within the interior of the pre-filled pod in a specific orientation by at least one grommet.

The regulator may be configured to apply a predetermined amount of pressurized air to the transitionable stopper through the use of a valve device. The source of air or gas may be engaged with an access port formed in the regulator. The source of air or gas may be a standard syringe, such that depression of a plunger rod of the standard syringe pressurizes the regulator. The regulator may further include an indicator that is activated to indicate that the regulator has a predetermined amount of pressurized air that is sufficient to deliver a complete dose. The regulator may include an activation trigger configured to be aligned with an indicator for allowing a user to set the regulator to deliver a metered dose.

These and other features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic partial cross-sectional side view of a pre-filled pod assembly and a female luer connector in accordance with an embodiment of the present invention.

FIG. **2** is a schematic partial cross-sectional side view of the pre-filled pod assembly joined with the female luer connector of FIG. **1** in accordance with an embodiment of the present invention.

FIG. **3** is a schematic partial cross-sectional side view of the pre-filled pod assembly and female luer connector of FIG. **2** engageable with a standard syringe in accordance with an embodiment of the present invention.

FIG. **4** is a schematic partial cross-sectional side view of the pre-filled pod assembly and female luer connector of FIG. **2** engaged with the standard syringe of FIG. **3** in an initial position in accordance with an embodiment of the present invention.

FIG. **5** is a schematic partial cross-sectional side view of the pre-filled pod assembly and female luer connector engaged with the standard syringe of FIG. **4** in an activated position having the contents of the pod assembly partially expelled therefrom in accordance with an embodiment of the present invention.

FIG. **6** is a schematic partial cross-sectional side view of a pre-filled pod having an alternative female luer connector in accordance with an embodiment of the present invention.

FIG. **7** is a schematic partial cross-sectional side view of the pre-filled pod assembly joined with the female luer connector of FIG. **6** in accordance with an embodiment of the present invention.

FIG. **8** is a schematic partial cross-sectional side view of the pre-filled pod assembly and female luer connector of FIG. **7** engaged with a standard syringe in accordance with an embodiment of the present invention.

FIG. **9** is a side view of a pre-filled pod assembly and female luer connector engaged with a standard syringe in an initial position in accordance with an embodiment of the present invention.

FIG. **10** is a side view of the pre-filled pod assembly and female luer connector engaged with a standard syringe of FIG. **9** in an activated position in accordance with an embodiment of the present invention.

FIG. **11** is a perspective view of a pre-filled pod engaged with a regulator in accordance with an embodiment of the present invention.

FIG. **12** is a perspective view of the pre-filled pod and regulator of FIG. **11** engaged with a standard syringe in an initial position in accordance with an embodiment of the present invention.

FIG. **13** is a perspective view of the pre-filled pod and regulator engaged with a standard syringe of FIG. **12** in the activated position in a first cycle in accordance with an embodiment of the present invention.

FIG. **14** is a perspective view of the pre-filled pod and regulator engaged with a standard syringe of FIG. **12** in the initial position in a second cycle in accordance with an embodiment of the present invention.

FIG. **15** is a perspective view of the pre-filled pod and regulator engaged with a standard syringe of FIG. **12** in the activated position in a second cycle in accordance with an embodiment of the present invention.

FIG. **16** is a perspective view of the pre-filled pod and regulator in an initial position having the "off" speed selected in accordance with an embodiment of the present invention.

FIG. **17** is a perspective view of the pre-filled pod and regulator of FIG. **16** in an initial position having a specified speed selected in accordance with an embodiment of the present invention.

FIG. **18** is a perspective view of the pre-filled pod and regulator of FIG. **16** in an activated position having a specified speed selected in accordance with an embodiment of the present invention.

FIG. **19** is a cross-sectional front view of a pre-filled pod and regulator engaged with a standard syringe and a dispensing assembly in an initial position in accordance with an embodiment of the present invention.

FIG. **20** is a cross-sectional front view of the regulator of FIG. **19** in accordance with an embodiment of the present invention.

FIG. **21** is a cross-sectional front view of a pre-filled pod and regulator engaged with a standard syringe and a dispensing assembly of FIG. **19** in an activated position in accordance with an embodiment of the present invention.

FIG. **22** is a cross-sectional front view of the regulator of FIG. **21** in accordance with an embodiment of the present invention.

FIG. **23** is a cross-sectional front view of a pre-filled pod and regulator having an interior glass capsule in an initial position in accordance with an embodiment of the present invention.

FIG. **24** is a cross-sectional front view of a pre-filled pod and regulator having an interior glass capsule in an activated position in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION

For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

Reference is now made to FIGS. **1-5**, which depict a pre-filled pod assembly **10** which is adapted for dispensing and delivery of a fluid. The pre-filled pod assembly **10** includes a pre-filled pod **12** and a female luer connection **14** adapted for engagement with a portion of the pre-filled pod **12**. The pre-filled pod **12** has a distal end **16** and a proximal end **18** and a sidewall **20** extending therebetween defining an interior **22**. The pre-filled pod **12** also includes a transitionable stopper **24** disposed at least partially within the interior **22** of the pre-filled pod **12**. The transitionable stopper **24** is dimensioned for interference fit within the interior **22** of the pre-filled pod **12** to create a substantially liquid impermeable seal against the interior of the sidewall **20**. In one embodiment, the transitionable stopper **24** may be a polymeric material, rubber composition, hard plastic composition, and the like.

In one embodiment, the pre-filled pod **12** is adapted for containing a substance **13** therein, such as a fluid medication, sterile water, saline, fluid narcotic, or other controlled substance. The interior **22** of the pre-filled pod **12** may have any suitable storage volume for housing a substance therein, such as 2-3 ml. It is noted that the storage volume may be exclusive of the volume occupied by the transitionable stopper **24**. In one embodiment, the transitionable stopper **24** has a distal end **26** and a proximal end **27**, with the suitable storage volume defined between the interior **22** of the sidewall **20** of the pre-filled pod **12** and the distal end **26** of the transitionable stopper **24**. In this configuration, the transitionable stopper **24** may be made of a substantially non-reactive material so as not to interfere or interact with the substance **13** disposed within the pre-filled pod **12**. Alternatively, a non-reactive coating and/or non-reactive seal member (not shown) may be disposed adjacent the distal end **26** of the transitionable stopper **24** to provide additional sealing between the transitionable stopper **24** and the contents of the pre-filled pod **12**. The sidewall **20** of the pre-filled pod **12** may also be made of a substantially non-reactive material, such as glass, one or more polymeric material, and/or a polymeric material molded over glass and may optionally be coated with a barrier or other non-reactive coating.

The distal end **16** of the pre-filled pod **12** may include a dispensing tip **28** having a fluid passage **30** therethrough in communication with the interior **22** of the pre-filled pod **12**. When suitable pressure is applied to the substance **13** of the interior **22** of the pre-filled pod **12**, at least a portion of the substance **13** may pass through the fluid passage **30** for expulsion from the pre-filled pod **12**, as will be described herein. The dispensing tip **28** may also include a removable cap **32** for sealing the fluid passage **30**.

The proximal end **18** of the pre-filled pod **12** may include a receiving cavity **34** adapted for engagement with a female luer connection **14**. In one configuration, at least a portion of the female luer connection **14** is adapted for receipt within the receiving cavity **34**. A forward end **40** of the female luer connection **14** may include a seal **42**, such as an "O-ring", for internal sealing against a portion of the receiving cavity **34**. Optionally, a portion of the proximal end **18** of the pre-filled pod **12** may also include a sealing member **36** for receipt within a portion of the female luer connection **14**, as shown in FIG. **2**. The female luer connection **14** includes a fluid passage **44** therethrough, such that fluid, either in the form of a gas or liquid, may pass through the fluid passage **44** and contact the proximal end **27** of the transitionable stopper **24**.

Engagement of the female luer connection **14** and the pre-filled pod **12** may be accomplished by applying a force in the direction of the arrows A shown in FIGS. **1-2**. It is noted that in certain configurations, the engagement of the female luer connection **14** with the pre-filled pod **12** occurs after aseptic fill and terminal sterilization of the pre-filled pod **12** and indwelling substance **13**. As shown in FIG. **2**, a captive air chamber **48** may be formed between the female luer connection **14** and the proximal end **27** of the transitionable stopper **24**. This captive air chamber **48** may be open to the atmosphere. Optionally, a disk member **50**, such as a metalized disk, may be provided adjacent the proximal end **27** of the transitionable stopper **24** to assist in barrier and/or structural integrity of the transitionable stopper **24**.

As shown in FIGS. **3-5**, a source of air or gas, such as a standard syringe assembly **60**, may be engaged with the female luer connection **14**. The standard syringe assembly **60** may include a syringe barrel **62** defined by barrel wall **64** extending between a forward or distal end **66** and a rearward or proximal end **68**, thereby defining interior chamber **70** of syringe barrel **62**. Syringe barrel **62** may be in the general form of an elongated cylindrical barrel as is known in the art for the general shape of a hypodermic syringe. Forward end **66** of syringe barrel **62** includes an outlet opening **72** which is provided in fluid communication with the fluid passage **44** of the luer connection **14**, such that once engaged, the interior chamber **70** of the syringe barrel **62** is provided in fluid communication with the fluid passage **44** of the luer connection **14**. As used herein, the term "fluid" is intended to include both gases and liquids.

The syringe barrel **62** may include markings, such as graduations on the wall thereof, for providing an indication as to the level or amount of fluid contained within syringe barrel **62**. Such markings may be provided on the external wall, the internal wall, or integrally formed or otherwise within the wall of syringe barrel **62**. The syringe barrel **62** may further include a finger grasping surface, such as finger flanges **74** for providing finger support surfaces for a user during use of syringe assembly **60**. The syringe assembly **60** further includes a plunger assembly **76**, a portion of which is disposed at least partially within syringe barrel **62**. Plunger assembly **76** provides a mechanism for dispensing fluid contained within the interior chamber **70** of syringe barrel **62**. In particular, plunger assembly **76** includes a plunger rod **78** connected to a plunger head **80** adapted for expelling contents of the interior chamber **70** when the plunger rod is pushed in the direction of arrow B, as shown in FIG. **5**.

A dispensing cannula **82**, such as a patient needle or IV system needle, may be adapted for engagement with the distal end **16** of the pre-filled pod **12**, such as the dispensing tip **28**. As shown in FIG. **5**, when the plunger rod **78** is deployed in the direction of arrow B, fluid, preferably air, is expelled from the interior chamber **70** of the syringe barrel **62** and directed through the fluid passage **44** of the luer connection **14**. The fluid exiting the interior chamber **70** is pressurized by the action of the plunger rod **78** and contacts the proximal end **27** of the transitionable stopper **24** with sufficient pressure to advance the transitionable stopper **24** from an initial position, as shown in FIG. **4**, to an activated position, shown in FIG. **5** in which the substance **13** of the pre-filled pod **12** is expelled from the pre-filled pod. It is noted that the syringe assembly **60** does not directly contact any of the substance **13** contained within the pre-filled pod **12** and thus, after use of the pre-filled pod **12**, the syringe assembly **60** may be re-used. It is also noted that the interior chamber **70** of the syringe assembly **60** may utilize either a gas or a liquid, or both, to advance the transitionable stopper **24**. In another configuration, a vent (not shown) may be provided in the proximal end **18** of the pre-filled pod **12** to allow injection of a liquid into the captive air chamber **48** to allow the attachment of a standard syringe assembly **60** and subsequent drug delivery pump (also not shown) for metered dosing.

An advantage of using a pre-filled pod **12** of the present invention is the small storage space of the pre-filled pod. For example, a large disadvantage of a pre-filled syringe with a vaccine is that most vaccines need to be kept in cold storage during transport and prior to use. The small size of the pre-filled pods of the present invention allows pre-filling with a pre-loaded dose of vaccine that may be easily kept in cold storage. Most institutions have limited space of cold storage and this design facilitates low storage space. Accordingly, when the pre-filled pods are used for pre-filling for "developing countries" in support of vaccination campaigns, the reduced size of the device for cold storage transport, and the lack of a plunger rod being attached to the stopper, makes the device less desirable for improper re-use of a contaminated product.

Additional advantages of the present invention are a reduction in the number of components required to complete a dispensing of a substance, and that a medical practitioner cannot draw the transitionable stopper **24** toward the proximal end of the pre-filled pod. It is also noted herein that the dispensing cannula **82** and the female luer connection **14** may be appropriately adapted for engagement with any standard system conventionally known. For example, many pharmaceutical preparations are manufactured using syringe filling equipment along with nest filling equipment where the syringes are supplied in a nest holder to the pharmaceutical manufacturer. The active vial design of the present invention with the included flange on the open end and standard stopper design facilitates the use of existing syringe filling equipment.

Referring to FIGS. **6-8**, an alternative connection between the proximal end **18**A of the pre-filled pod **12**A and the female luer connection **14**A is shown. In this configuration, the female luer connection **14**A may be dimensioned to at least partially recess into the proximal end **18**A of the pre-filled pod **12**A to further reduce the overall operating dimensions of the pre-filled pod assembly **10**A. As shown in FIG. **8**, the syringe assembly **60**A may also be at least partially recessed into the proximal end **18**A of the pre-filled pod **12**A. In a further configuration, with reference to FIG. **7**, the female luer connection **14**A may also include a vent **77** adapted to allow gas to escape from the captive air chamber **48**A but does not allow passage of liquid therethrough. It is contemplated herein that the use of a saline filled syringe assembly **60**A could allow the pre-filled pod **12**A to evacuate air and be used on a conventional hospital pump with a liquid filled behind the transitionable stopper **24**A to advance the transitionable stopper **24**A in a distal direction in accordance with pump movement.

It is contemplated herein that the pre-filled pod **12**, **12**A of the present invention is suitable for use in drug administration via an IV, dilution into an IV system, and through safety needles that can be attached for injection.

Referring to FIGS. **9-10**, the pre-filled pod **12** of the present invention may be adapted to indicate to the user that a certain amount of substance **13** has been expelled by markings **90** provided on a portion of the pre-filled pod **12**. Accordingly, the medical practitioner may observe that a complete dose corresponds to a specified amount of substance. Referring to FIG. **9**, the pre-filled pod **12** is shown in the initial unused position. Referring to FIG. **10**, the pre-filled pod **12** is shown having a portion of the substance partially expelled from the

pre-filled pod **12** upon application of force to the plunger rod **78** of the syringe assembly **60**. It is appreciated herein that although the pre-filled pod **12** and the syringe assembly **60** are shown in the drawings in a substantially horizontal orientation, in use, the pre-filled pod **12** and the syringe assembly **60** will likely be employed in an angled configuration, such as about 60° with respect to vertical.

Referring to FIGS. **11-15**, the pre-filled pod **12**B may be used as described above in conjunction with a regulator **100** for regulating the amount of substance **13**B expelled from the pre-filled pod **12**B over a predetermined period of time. In certain situations, a medical practitioner may be required to introduce a substance **13**B, such as a medication, narcotic, and the like, into an IV system or other similar treatment delivery system over a long period of time. Some dosing deliveries may require that a medical practitioner deliver a complete dose over a period of time on the order of five minutes by manually advancing a syringe plunger in incremental steps. This slow pacing can be difficult for a hurried medical practitioner to maintain, and consistency may be lost by human error. The regulator **100** of the present invention may be provided in fluid communication with the transitionable stopper **24**B in order to provide for a constant expulsion of substance **13**B from the pre-filled pod **12**B over a predetermined length of time without requiring a medical practitioner to determine the pacing of the dose. As shown in FIGS. **12-14**, the regulator **100** coupled with the pre-filled pod **12**B of FIG. **11**, is shown coupled with a standard syringe assembly **60**B such that fluid, such as air, within the interior chamber **70** of the syringe assembly **60**B is directed into the regulator **100**, the mechanism of which will be discussed herein.

Referring to FIGS. **12-13**, in use the medical practitioner determines the appropriate amount of dose that should be provided over a specified period of time. The medical practitioner may then deploy the plunger rod **78**B or set an automatic plunger deployment system (not shown) to deploy the plunger rod **78**B. The regulator **100** of the present invention prevents over-dosing within a specified period of time by restricting the advancement of the transitionable stopper **24**B. In certain situations, a single deployment of the plunger rod **78**B of the syringe assembly **60**B may be sufficient to properly deliver the dose of substance **13**B by pressurizing the regulator **100** in a single or first cycle. In other situations, a second cycle, shown in FIGS. **14-15**, may also be required. In the second cycle, the medical practitioner re-deploys the plunger rod **78**B of the syringe assembly **60**B. After completion of an appropriate number of cycles, such as after completion of the second cycle, the indicator **102**, shown in FIG. **15**, may be activated to indicate that the regulator **100** has sufficient pressure to deliver a complete dose over a specified and predetermined period of time.

Referring to FIGS. **16-18**, the interval setting of the regulator **100** may be established by the medical practitioner. During use, the medical practitioner may set the regulator from the "off" position, shown in FIG. **16**, to a metered dose position, shown in the pre-use state in FIG. **17**, and in the after-use or dispensed state in FIG. **18**. The medical practitioner may align an activation trigger **108** with a corresponding indicator **110** positioned on a moveable portion **112** of the regulator **100**. The corresponding indicator **110** may include indicia, such as 20 ml/hr, which indicates to the medical practitioner the appropriate setting for expelling the substance **13**B.

Referring to FIGS. **19-22**, the metered dose dispensing of the regulator **100** is accomplished by providing the regulator in engagement with the pre-filled pod **12**B such that the regulator **100** is in fluid communication with the proximal end **18**B of the pre-filled pod **12**B. A standard syringe assembly **60**B is provided in fluid engagement with a first access port **120** of the regulator **100** such that the outlet opening **72**B is aligned with the first access port **120**. The housing **121** of the regulator **100** includes a cavity **122** aligned with the first access port **120** including a transitionable valve member **124**. During operation, as shown in FIGS. **19-20**, the plunger rod **78**B of the syringe assembly **60**B is deployed, as shown in FIGS. **12-13**, which directs pressurized gas into the first access port **120**. During the introduction of pressurized gas into the first access port **120**, the transitionable valve member **124**, such as a ball check valve, is transitioned to allow passage of air into the regulator **100**. After injecting all of the gas into the first access port **120** of the regulator **100**, the clinician may aspirate the syringe assembly **60**B and re-deploy the plunger rod **78**B, as shown in FIGS. **14-15**. Referring to FIGS. **21-22**, during aspiration, a second transitionable valve member **130**, such as a ball check valve, is transitioned to allow ingress of air through a second access port **125** from the atmosphere.

Referring specifically to FIG. **20**, during deployment of the plunger rod **78**B, the transitionable valve member **124** is deployed to allow air to pass into the regulator **100** and to allow pressurization of the regulator **100**. Referring to FIG. **22**, when pressurized air is not being directed into the regulator **100** by deployment of the plunger rod **78**B, then the transitionable valve member **124** blocks the escape of air from the regulator **100** by sealing the pathway **123**, shown in FIG. **20**. During aspiration, as shown in FIG. **22**, the second transitionable valve member **130** is deployed to allow air to pass into the regulator **100** and interior chamber of the syringe assembly **60**B through pathway **129**. Referring to FIG. **20**, when air is not being withdrawn from atmosphere into the regulator **100**, the second transitionable valve member **130** blocks the escape of air from the regulator **100** by sealing the pathway **129**, shown in FIG. **22**. After the regulator **100** is properly pressurized, the indicator **102**, shown in FIG. **15**, is activated and the medical practitioner may disconnect the syringe assembly **60**B from the regulator **100**. The medical practitioner then aligns the activation trigger **108** with a corresponding indicator **110** of the regulator **100**, as shown in FIGS. **16-18**, and the regulator **100** introduces a proper pressure to the transitionable stopper **24**B to expel the substance **13**B at an appropriate dosing. The regulator **100** ensures that a proper amount of pressurized air is applied to the transitionable stopper **24**B throughout the metered dosing by suitable valve means. Optionally, the indicator **102** may be adapted to relieve pressure from within the regulator **100** in the event that the regulator **100** is over pressurized. As shown in FIG. **22**, an undercut **103** at the base of the indicator **102** may allow air to leak between the indicator **102** and the surrounding housing **104** once the indicator **102** is deployed in a direction shown by arrow D of FIG. **22** past a specified point. In another embodiment, a spring **107** may be disposed within the regulator **100** between a lower end **105** of the indicator **102** and a contact surface **106** of the regulator **100** to bias the indicator **102**. Once the indicator **102** is deployed against the bias of the spring **107**, air may pass from within the regulator **100** to the atmosphere through the undercut **103** between the indicator **102** and the surrounding housing **104**. In accordance with an additional embodiment, the syringe assembly may be replaced by a finger pump, a longitudinally collapsing bellows, or a "squeeze ball" mechanism.

In accordance with yet another embodiment, as shown in FIGS. **23-24**, a pre-filled pod assembly **200** and regulator **201** are shown, as described herein, with the exception that the pre-filled pod assembly **200** includes a capsule **220** for con-

taining a substance **202** disposed therein, such as fluid medication, sterile water, saline, fluid narcotic, or other controlled substance. The pre-filled pod assembly **200** may include a pre-filled pod **210** having a distal end **211**, a proximal end **212**, and a sidewall **214** extending therebetween defining an interior **216**. The capsule **220** is disposed within the interior **216** of the pre-filled pod **210** and may be held within the interior **216** in a specific orientation by at least one grommet **217**, such as a rubber grommet **217**. The capsule **220** may include a first opening **218** adjacent a first end **221** of the capsule **220** and a second opening **222** adjacent a second end **223** of the capsule **220**. The first opening **218** may be aligned with the proximal end **212** of the pre-filled pod **210** and the second opening **222** may be aligned with the distal end **211** of the pre-filled pod **210**. In a further embodiment, the pre-filled pod **210** further includes a transitionable stopper **230**, as described herein. The first opening **218** of the capsule **220** may be aligned such that in operation, as the transitionable stopper **230** is advanced or moved in a downward direction, as shown in FIG. **24**, air **232** disposed over the capsule **220**, as shown in FIG. **23**, is pressurized and enters the capsule **220**, as shown in FIG. **24**, via the first opening **218**. The pressurized air **232** entering the capsule **220** expels the substance **202** from within the capsule **220** through the second opening **222** and out the pre-filled pod assembly **200**.

As shown in FIG. **24**, at least a portion of the transitionable stopper **230** seals the first opening **218**. In one embodiment, the volume of substance **202** is greater than the volume of air **232**, which limits expulsion of the air **232** from the capsule **220** of the pre-filled pod **210**. In order to ensure that air is not expelled from the capsule **220**, in certain embodiments, the pre-filled pod **210** is oriented such that the regulator **201**, or optional syringe assembly (not shown), is always higher than the pre-filled pod **210**. In another configuration, the second opening **222** of the capsule **220** is dimensioned such that due to surface tension forces, the substance **202** does not exit the second opening **222** unless sufficient pressure is applied to the capsule **220** through the first opening **218**. Optionally, an air bubble **240** may be provided adjacent the second opening **222** to further limit expulsion of the substance **202** absent applied pressure as discussed herein. As such, the substance **202** of the capsule **220** is isolated from the other components of the pre-filled pod assembly **200**. In a further embodiment, lubrication of the capsule **220** is not required as the pressurized air provides the mechanism for expelling the substance **202** from the capsule **220**. This may be advantageous as silicone oils conventionally used to lubricate the syringe assembly (not shown) or regulator **201** will not enter the capsule **220**, thus limiting contamination of the substance **202**.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

The invention claimed is:

1. A pre-filled pod assembly comprising:

a pre-filled pod having a distal end, a proximal end, and a sidewall extending therebetween defining an interior;

a transitionable stopper disposed within the interior of the pre-filled pod; and

a regulator coupled to the proximal end of the pre-filled pod and provided in fluid communication with the interior of the pre-filled pod comprising:

an inlet, an outlet, and a housing defining a cavity between the inlet and the outlet:

a valve that controls flow through the inlet and into the cavity; and

an outlet valve that controls flow out of the cavity and through the outlet;

wherein when the valve and the outlet valve are both in a closed position, the cavity is sealed, and when the valve is in an open condition, pressurized gas or fluid may enter the cavity, and when the outlet valve is in an open position, pressurized gas or fluid stored in the cavity may pass through the outlet, and wherein the outlet of the regulator is in fluid communication with the interior of the pod such that pressurized gas or fluid flowing from the outlet of the regulator enters the interior of the pod advancing the transitionable stopper from an initial position to an activated position in which at least a portion of a fluid contained within the interior of the pre-filled pod is advanced therefrom.

2. The pre-filled pod assembly of claim **1**, wherein the outlet valve supplies pressurized gas or fluid to the transitionable stopper in a predetermined amount.

3. The pre-filled pod assembly of claim **1**, further comprising a standard syringe in fluid communication with the inlet of the regulator, such that depression of a plunger rod of the standard syringe opens the valve and forces pressurized gas into the cavity of the regulator.

4. The pre-filled pod assembly of claim **3**, further comprising a second valve controlling flow from an air or fluid source into the inlet, wherein aspiration of the syringe opens the second valve allowing air or fluid to enter the syringe.

5. The pre-filled pod assembly of claim **4**, wherein the air or fluid source is the atmosphere surrounding the regulator.

6. The pre-filled pod assembly of claim **4**, wherein repeated depression and aspiration of the syringe when the outlet valve is closed causes pressure to build in the cavity.

7. The pre-filled pod assembly of claim **1**, wherein the regulator further comprises an indicator that is activated when a pressure of pressurized gas or fluid stored in the cavity is sufficient to advance the desired amount of liquid from the interior of the pod.

8. The pre-filled pod assembly of claim **1**, wherein the regulator comprises an activation trigger configured to be aligned with an indicator for allowing a user to open the outlet valve and set the flow through the outlet valve to advance the liquid at a metered rate.

9. The pre-filled pod assembly of claim **1**, wherein introduction of pressurized gas or fluid into the inlet builds pressure in the cavity when the outlet valve is closed and closing the inlet valve causes the pressurized gas or fluid in the cavity to be stored in a pressurized state.

10. The pre-filled pod assembly of claim **1**, wherein the cavity has a fixed volume.

* * * * *